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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,019	09/05/2003	Shrirang Netke	11957/59	9038
7590 KENYON & KENYON One Broadway New York, NY 10004		02/07/2007	EXAMINER CHOI, FRANK I	
			ART UNIT 1616	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/07/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/657,019

Applicant(s)

NETKE ET AL.

Examiner

Frank I. Choi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 June 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/26/2006</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Amendment***

The Amendment (6/26/2006) to the Specification is improper. The Amendment to the Specification must be done by replacement paragraphs, or sections or substitute specification. See 37 CFR 1.121 (b).

### ***Drawings***

The Examiner acknowledges the submission of replacement drawings (6/26/2006) to correct the "Figure" to "Fig.", however, the replacement drawings raise further issues as follows:

The drawings are objected to because Figs. 1-3 are unclear. The images of the bones are not sufficiently distinct from the background (the original drawings are better). The background of Fig. 3 obscures the data points. The background of the graph is too dark and obscures the data points. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will

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be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE 202 07 569 U1 in view of Rosenberg et al. (US Pat. 6,579,544), Brown et al. (US Pat. 6,528,042), Fini et al., Ibsen et al., Dollwet et al. and Dodds et al..

DE 202 07 569 U1 discloses a dietary supplement containing lysine, proline, Vitamin C, copper, Vitamin B6 and Vitamins A, D3, B1, B2, niacin, folic acid, B12, biotin, pantothenic acid and calcium, phosphorous, magnesium, zinc, selenium, manganese, chromium, molybdenum, potassium, hesperidin, arginine, cysteine, myo-inositol, carnitine, ubiquinone and bioflavonoids (See entire document).

Rosenberg et al. discloses that vitamin C is essential for the healing of bone fractures and that such fracture heal slowly in a patient deficient in vitamin C (Column 9, lines 32-54). It is disclosed that bioflavonoids promote vitamin C activity and include hesperidin which is found in the rinds of oranges and lemons and proanthocyanidins (Column 18, lines 11-26).

Brown et al. disclose that the combination of flavonoids or flavonoids and synergists, where the flavonoid can be hesperidin or pycnogenol and the synergist can also be a flavonoid,

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carnitine, lysine, arginine or tocopherols and that pycnogenol and hesperedin are used for ameliorating injuries (Column 19, lines 20-68, Column 20, Column 21, lines 1-4).

Fini et al. disclose that the rationale for using lysine in fractures is that lysine stimulates intestinal calcium absorption and renal conservation and cross-linking process of bone collagen (page 214). It is disclosed that L-proline acts as a substrate for collagen synthesis (page 214).

Ibsen et al. disclose that administered proline is used during bone healing (Pages 803, 804).

Dollwet et al. disclose that copper supplementation increases the rate of bone healing (Abstract).

Dodds et al. disclose that delayed fracture healing was observed in vitamin B6 deficient rate (Abstract).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose a method for facilitating bone healing in a mammal by administering the combination of lysine, proline, ascorbic acid, copper and vitamin B6. However, the prior art amply suggests the same as the prior art discloses the same as a nutritional supplement, that vitamin C is necessary for healing bone fractures, lysine increases calcium in the body and stimulates cross-linking of collagen, proline is used as a substrate for collagen synthesis and in bone healing, that vitamin B6 deficiency leads to delayed fracture healing and that pycnogenol is suitable for use in compositions for ameliorating injuries. As such, one of ordinary skill in the art would have been motivated to administer the composition disclosed in DE 202 07 569 U1 wherein the flavonoids include pycnogenol with the expectation that the composition would be effective in increasing the rate of bone healing.

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The Examiner has duly considered the Applicant's arguments but deems them moot in light of the new grounds of rejection. Contrary to the Applicant's arguments, the Examiner has provided motivation to combine lysine, proline, ascorbic acid, copper and vitamin B6 as indicated above. The '042 patent discloses the use of flavonoids in the treatment of injuries. Fractures are injuries, as such, there is motivation to combine the '042 patent with the other prior art.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

#### **Conclusion**


A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Thursday, Friday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Dr. Johann Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi  
Patent Examiner  
Technology Center 1600  
February 1, 2007



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